



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DATE: November 6, 2006

TO: Randall Lutter, Ph.D.
Associate Commissioner for Policy and Planning
Food and Drug Administration

THROUGH: Vince Tolino
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

FROM: Igor Cerny, Pharm.D. LSI
Director, Advisors and Consultants Staff
Center for Drug Evaluation and Research

SUBJECT: Conflict of Interest Waiver for Andrew Leon, Ph.D.

I am writing to request a waiver for Andrew Leon, Ph.D., a member of the Psychopharmacologic Drugs Advisory Committee, from the conflict of interest prohibitions of 18 U.S.C. §208(a). Waivers under section 208(b)(3) may be granted by the appointing official where "the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest involved" and where the individual has made a disclosure of the financial interests at issue. We have determined that you are the appointing official for purposes of section 208. Therefore, you have the authority to grant Andrew Leon, Ph.D., a waiver under 18 U.S.C. §208(b)(3).

Section 208(a) prohibits Federal executive branch employees, including special Government employees, from participating personally and substantially in matters in which the employee, or any other person whose interests are imputed to the employee under 18 U.S.C. §208, has a financial interest. Since Dr. Leon is a special Government employee, he is under a statutory obligation to refrain from participating in an official capacity in any particular matter having a direct and predictable effect on a financial interest attributable to him, his spouse, minor child, or general partner; an organization or

entity for which he serves as an officer, director, trustee, general partner, or employee; and, a person with whom he is negotiating for, or has an arrangement concerning, prospective employment.

The functions of the Psychopharmacologic Drugs Advisory Committee, as stated in its Charter, are to review and evaluate data concerning the safety and effectiveness of marketed and investigational human drug products for use in the practice of psychiatry and related fields and make appropriate recommendations to the Commissioner of Food and Drugs.

Dr. Leon has been asked to participate in all official matters concerning the discussions of the results of the FDA ongoing meta-analysis of suicidality data from adult antidepressant trials. This is a particular matter involving specific parties.

Dr. Leon has advised the Food and Drug Administration (FDA) that he has a financial interest that could potentially be affected by his participation in this matter. Dr. Leon serves as a member of _____ Data Safety Monitoring Board for an investigational agent for use in the treatment of schizophrenia and mania. _____, a division of _____ markets _____, a product that could be affected by the committee's discussion.

As a member of the Psychopharmacologic Drugs Advisory Committee, Dr. Leon potentially could become involved in matters that could affect his financial interest. Under 18 U.S.C. §208(a), he is prohibited from participating in such matters. However, as noted above, you have the authority under 18 U.S.C. §208(b)(3) to grant a waiver permitting Dr. Leon to participate in such matters as you deem appropriate.

For the following reasons, I believe that it would be appropriate for you to grant a waiver to Andrew Leon, Ph.D., which would permit him to participate in the matters previously described.

First, Dr. Leon's personal financial interest is not so substantial as to preclude his participation in the matter described previously. Dr. Leon receives minimal compensation for his services.

Second, Dr. Andrew Leon is a standing member of the Psychopharmacologic Drugs Advisory Committee. Dr. Leon is the only biostatistician for this meeting where the primary goal is to evaluate meta analysis data. Dr. Leon's requisite expertise in antidepressant clinical trials and biostatistics will be depended upon by the committee in providing significant feedback in generating a sound recommendation to the FDA. Dr. Leon's participation in the previous SSRI pediatric suicidality meeting was of great significance and his presence at this meeting will lend much needed continuity to this one-day meeting.

Finally, the Federal Advisory Committee Act requires that committee memberships be fairly balanced in terms of the points of view represented and the functions to be performed by the various advisory committee members and Dr. Leon's participation in will contribute to the balance of views represented and the diversity of opinions and expertise. The Committee's intended purpose would be significantly impaired if the agency could not call upon experts who have become eminent in their fields, notwithstanding the financial interests and affiliations they may have acquired as a result of their demonstrated abilities. Dr. Andrew Leon is Professor of Biostatistics in Psychiatry, Weill Medical College of Cornell University. Dr. Leon's primary interests include quantitative methods in mental health research and issues in psychometrics. Dr. Leon is a member of several professional societies including the American Statistical Association, the Society for Clinical Trials and the International Biometric Society. I believe that Dr. Leon's participation will bring experience and knowledge that is essential to the committee's discussions and will help provide a foundation for developing advice and recommendations that are fair and comprehensive.

